

Abstracts

A61

services with the PCS ($p < 0.05$). **CONCLUSION:** The results of this study indicate that general health status and patient satisfaction are mutually exclusive variables. Further research is need to understanding which attributes of patient satisfaction are correlated with general health status.

PMCI7

MULTI-METHOD QUALITATIVE APPROACH TO DEVELOP COMPREHENSIVE PATIENT-REPORTED OUTCOME MEASURES: AN EXAMPLE FROM DENTAL CARE

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OBJECTIVES: There is no standard method for providing national benchmarks of dental care quality based on patient reports, largely, because it is difficult to create a survey that covers all topics important to various stakeholders (dentists, patients and dental care experts) while being short enough for practical use. The purpose of this project was to use a multi-stage qualitative research approach to involve stakeholders for the purpose of developing a tool that would have value to very different audiences. **METHODS:** Specific features of dental care were identified by a qualitative analysis of three, consecutive data collections: 1) a search of the dental care quality assessment literature (which was dominated by clinical studies); 2) audio-tapes of in-person interviews with dental care experts (primarily payers and policy makers); and 3) audiovisual-tapes of focus groups with dental patients. Questions to address each of 117 unique features were drafted and organized into 20 topic areas. A shorter version of this question list was created by choosing a subset of questions that addressed just seven (of 20) topic areas identified as the most critical aspects of care by both dental care experts and dental patients. Finally, in-depth, "think-aloud" interviews were used to determine the comprehensibility of the questions and to assess whether they were interpreted as intended. **RESULTS:** A 50-item questionnaire was developed that describes: Dentist Communication, Technical Quality of Care, Cleanliness of Office/Clinic, Treatment Outcome, Access to Necessary Care, Timely Access to Care, and Quality of Dental Plan. **CONCLUSION:** A rigorous program of qualitative research can be used to develop a content-valid, concise, yet comprehensive tool to provide data of potential value to a variety of stakeholders. Subsequent research will evaluate the statistical precision of data provided by this questionnaire in a pilot sample of approximately 2100 dental patients.

PMCI8

THE PROLABELS DATABASE: A NEW ON-LINE TOOL TO EXPLORE THE WORDING AND TYPES OF PRO INCLUDED IN APPROVED MEDICINAL PRODUCTS LABELS

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OBJECTIVES: Patient-reported Outcomes (PRO) are used in clinical studies to assess patients' treatment benefit. There is an increased interest in examining PRO claims included in approved product labels. To date, there is no single database summarizing PRO claims approved by the FDA or the EMEA by therapeutic area, type of PROs or sponsors. In order to provide easy access to this information, Mapi Research Trust and Mapi Values have developed the PROLabels database. **METHODS:** Summary Product Characteristics (SPC) of drugs approved through the centralized procedure were gathered from the EMEA website since January 1995. Approved labels of New Molecular Entities posted on the FDA CDER website since January 1998 were also examined. Only data pertaining to efficacy endpoints were considered. Once a PRO claim was identified in an approved label,

the corresponding product was added to the database. Further information displayed include: description of clinical studies supporting the claim, the product's pharmacological action, and data source. **RESULTS:** At the date of December 21, 2005, the database contains 121 records (57 from the FDA and 64 from the EMEA) for 91 different International Nonproprietary Names (INN). The five most represented therapeutic areas include nervous (32.0%), immune (24.0%), musculoskeletal (18.0%), genitourinary (14.8%), and respiratory (13.2%) systems. Signs and symptoms are the most frequently measured PROs while, HRQOL represents 20.7%. The database can be searched by INN, commercial name, marketing authorization holder, indication, PRO, approval date, and agency. **CONCLUSIONS:** The PROLabels database is a useful on-line tool to find which products have obtained a PRO claim when reviewed by the EMEA or the FDA. The database will be weekly updated. Other data sources will be added to include PRO approved through the mutual recognition/decentralized procedure in Europe and claim approved in Canada.

PMCI9

EVALUATING THE STRENGTH OF EVIDENCE OF CHANGE: A QUALIFIED CHANGE VS SIMPLE DIFFERENCE APPROACH TO QUALITY OF LIFE RATINGS

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OBJECTIVES: To determine if item-level examination of 12-month changes in quality of life (QOL) ratings gives qualitatively different evidence that QOL change occurred as compared to difference in total scores. **METHODS:** A total of 258 AD patients in a clinical trial of nonsteroidal anti-inflammatory agents responded to 13 QOL items at two visits 12 months apart. A simple difference (later-earlier) was calculated for total scores. A qualified change algorithm was applied to the items: ratings of "good" and "fair" were treated as indistinguishable and differences per item were classified as one of four possible outcomes: improved, worsened, stayed poor, and stayed "OK" (fair, good, excellent). A Toulmin diagram permits evaluation of the strength of evidence supporting a claim that "QOL changed"; this method was used to compare evidence of QOL change from the total score and item levels. **RESULTS:** "Significant loss of QOL" was observed in the treatment (each group mean < -1.0 , $p < 0.05$), but not the placebo (mean = -0.59 , $p > 0.3$), groups. Roughly 60% of all change in QOL items was worsening in each arm; 17-42% of all subjects experienced change in each item. **CONCLUSIONS:** Simple difference in total score over 12 months suggested little loss in QOL whereas qualifying change suggested that at least 17% of any group experienced change on every item with 60% of all change being worsening. A simple difference summarizes estimated change, obscuring evidence that change occurs. The Toulmin diagram suggests that more and stronger evidence of change was obtained in a qualified change approach, which reflects change as both improvement and worsening and contemplates alternative explanations for observed change. Qualified change provides more and stronger evidence of change in subjective measures such as QOL.